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10/582,564	03/26/2007	Katsumasa Nonoshita	BY0034YP	1616

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EXAMINER	
RODRIGUEZ-GARCIA, VALERIE	
ART UNIT	PAPER NUMBER
1626	
MAIL DATE	DELIVERY MODE
02/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,564	NONOSHITA ET AL.	
	Examiner	Art Unit	
	VALERIE RODRIGUEZ-GARCIA	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 24-26* is/are pending in the application.

4a) Of the above claim(s) *4-7, 11-16 and 25-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8-10, 17-19 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/26/2007, 12/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-23 were canceled by Applicants. Therefore, claims 1-19 and 24-26 are currently pending. The Examiner previously required an election of species on November 12, 2008 based on the set of claims dated March 26, 2007. In a telephone conversation on 01/23/2009 with applicant's representative, Mr. Richard Billups, it was clarified that the proper claims for prosecution are the amended claims dated June 12, 2006. Pending claims 1-19 and 24-26 are subject to Restriction/Election requirement.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

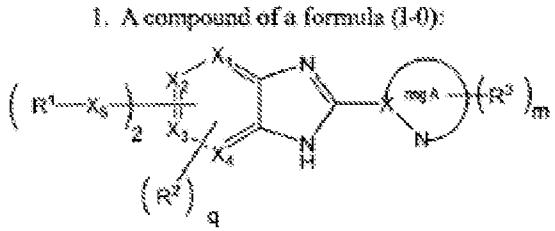
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-19 and 24, drawn to compounds of the formula I-0 and compositions.

II. Claims 25-26, drawn to methods of treatment.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the

same or corresponding special technical features for the following reasons: In this case, they do not share the same essential structural element(s) that define the "special technical feature" necessary to specify a contribution over the prior art. The compound of formula I, 

(I-0) , with its many and distinct variables, results in so many permutations that no common core can be constructed, thus the lack of a special technical feature is apparent. There is no special technical feature defining a contribution which each of the inventions, considered as a whole, makes over the prior art. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-II and between Markush species is broken.

Each invention listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though

is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have bee expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

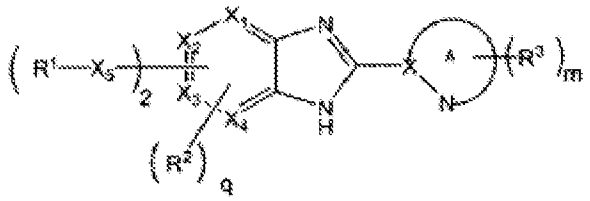
2. During a telephone conversation with Mr. Richard Billups on January 26, 2009 a provisional election was made **with traverse** to prosecute the invention of group I, claims 1-19 and 24, drawn to compounds. Affirmation of this election must made by applicant in replying to this Office action. Claims 25-26 are withdrawn from further consideration by the Examiner pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention.

A new Information Disclosure statement has been received on 12/12/2008 and considered.

Response to Restriction

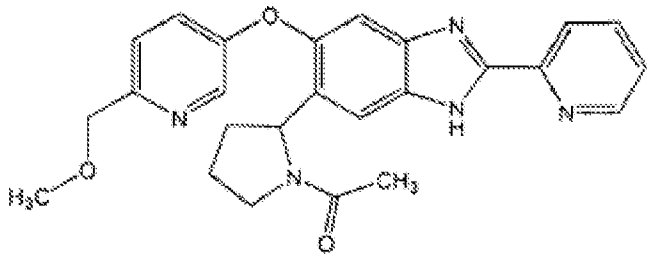
Applicant's election **with traverse** of Group I, claims 1-19 and 24, drawn to products represented by formula (I-0)

1. **(Original)** A compound of a formula (I-0):



(I-0)

and elected species (Applicants pointed to page 296, line 22 to find the elected species, however, the



specification ends in page 287) ,

in the reply filed on 12/12/2008 is acknowledged. Applicants arguments for the traversal are that the bicyclic core and the nitrogen-containing ring A together with the biological activity of the compounds as glucokinase activators provide common features among the species disclosed in the application, and that this constitutes a single inventive concept. The Examiner respectfully disagrees. The bicyclic core to which applicants refer to can be seen above in formula (I-0). There is no defined structure for the bicyclic core. The variables that make the core (X1, X2 X3 and X4) can be a carbon atom or nitrogen also substituted with

many other variables. These are all very distinct compounds. In addition, the nitrogen-containing ring A can be a 5 or 6 membered ring containing 1 to 3 heteroatoms consisting of nitrogen sulfur and oxygen in addition to the nitrogen already in the formula and the variable R1 can represent almost any hetero ring. Because of the many variables and permutations, no common core can be construed, thus the lack of special technical feature. In addition, the chemical artisan can not possibly infer that the very distinct structural features of the claimed compounds embrace the same biological activity. The various compounds involved differ in structure and element so much so as to be patentably distinct, i.e. a reference which anticipated the elected compounds claimed would not even render obvious the others. In accordance with 37 CFR 1.475 (a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Applicant has not presented evidence that the examined subject matter is patentably indistinct from the non-examined subject matter. Moreover, the sheer number of variables, their huge possibilities, and the number of permutations and combinations thereof result in compounds so numerous and diverse so as to be a burden just to classify, search, and examine.

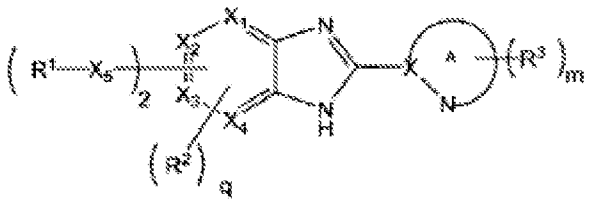
Thus, the requirement is still deemed proper and is therefore made **Final.**

Note

The elected species above has been found to be free of the prior art. However, the elected species is not embraced by at least claims 1 through 18. The variables $(R^1—X_5\text{--})_2$ *of claim 1 and their definition do not read on the*

elected species because currently (R^1—X_5--)$_2$ means two of the same variable (R^1—X_5--). However, to accelerate prosecution of the instant application, the examiner has expanded the search to include all claims relevant to the genus of the scope of the invention of the elected subject matter, for a first action on the merits..

The scope of the invention of the elected subject matter is as follows:



Compounds of Formula (I-0), (I-0) ,

depicted in claim 1, wherein: **X1, X2, X3 and X4 are each a carbon atom; (R^1—X_5--)$_2$** is interpreted as two different and separate substituens, **A, R^1 and R^1 are as defined; X_5 represents –O-, -S-, -S(O)-, -S(O)$_2$- and X_5 represents a bond.**

As a result of the election and the corresponding scope of the invention identified supra, claims 4-7, 11, 13-16, 24-26 and the remaining subject matter of claims 1-3, 8-10, 17-19 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups which are chemically recognized to differ in structure and function. The subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly. A reference which

anticipates the elected subject matter would not render obvious the withdrawn subject matter. In addition, the fields of search are not co-extensive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Pursuant to Applicant's response, claims 1-19 and 24-26 are pending, claims 20-23 are canceled and claims 4-7, 11-16 and 25-26 are withdrawn. Claims 1-3, 8-10, 17-19 and 24 (in part) are treated on the merits in this action. This is the first Office Action on the merits of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

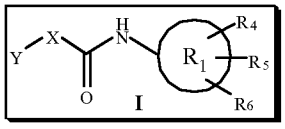
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 8-10, 17-19 and 24 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for substituted 2-heteroaryl benzimidazoles of the formula I-0, wherein A = pyridine, and R^1 (R^{11} in claim 8) and R^1 (R^{12} in claim 8) are phenyl, pyridine or pyrrole, does not reasonably provide enablement for the remaining scope of heterocycles which

include A as any 5-6 membered nitrogen containing aromatic heteroring or a twin-ring of the mentioned and R^1 and R^1 are any 5 to 6 membered nitrogen-containing heterocycles or any 4 to 7-membered nitrogen containing hetero ring respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention(s) commensurate in scope with these claims. Substituted 2-heteroaryl benzimidazoles of the formula I-02, as recited in claim 1, have not been adequately enabled in the specification. There is no reasonable basis for assuming that the myriad of compounds embraced by the all generic claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

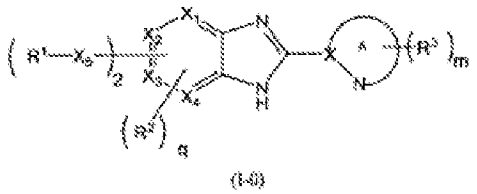
Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

(a) *Breadth of the claims* - the breadth of the claims includes all of the tens of thousands of substituted 2-heteroaryl benzimidazoles of the formula I, shown below, as well as the myriad of potential pharmaceutically acceptable salts, formulated



I

from these substituted benzimidazoles;



(I-0)

(b) *Nature of the invention* - the nature of the invention is clinical use of substituted 2-heteroaryl benzimidazoles of the formula I and the pharmacokinetic behavior of these substances in the human body as glucokinase activators for treatment of diabetes;

(c) *State of the prior art* - *Nature Reviews: Drug Discovery* offers a snapshot of the state of the drug development art. Herein, drug development is stated to follow the widely accepted Ehrlich model which includes: 1) development of a broad synthetic organic chemistry program; 2) subsequent testing of compounds in an appropriate laboratory model for the disease to be treated; and 3) screening of compounds with low toxicity in prospective clinical trials (Jordan, V. C. *Nature Reviews: Drug Discovery,* 2, **2003**, p. 205);

(d) *Level of one of ordinary skill in the art* - the artisans synthesizing applicant's substituted 2-heteroaryl benzimidazoles of the formula I -0 would be a collaborative team of synthetic chemists and/or health practitioners, possessing a Ph.D., M.D. or Pharm.D. and several years of professional experience;

(e) *Level of predictability in the art* - Synthetic organic chemistry is quite unpredictable (*In re Marzocchi and Horton* 169 USPQ at 367 ¶ 3). The following excerpt is taken from Dörwald, which has extreme relevance to the substituted 2-heteroaryl benzimidazoles of the formula I-0 (Dörwald, F. Zaragoza. *Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design*, Weinheim: WILEY-VCH Verlag GmbH & Co. KGaA, **2005**, Preface):

Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why.

Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of

> *complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work.*
>
> *Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious).*

(f) *Amount of direction provided by the inventor* – The inventors disclose methods on how to make their preferred compounds (found in some pages from p. 72 through 285). However, the compounds made are not representative of the instant scope but are closer to each other than to the remaining scope. The specification is not adequately enabled as to how to make and use <u>any</u> compounds generated of the generic formula I-0. The specification has no teaching as to how to make and use the compounds bearing groups which are highly reactive and would react with other functional groups and/or become susceptible to the environment to which they are exposed. The specification has no suggestion of how to make these highly reactive compounds and how to use them. The presence of reactive groups is chemically incompatible with the method of use embraced in the instant claims as well. Also, note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative."

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(g) *Existence of working examples* - applicant has provided general guidance (p.45-71) to make the generic 2-heteroaryl benzimidazoles of the formula I-0. GK activating Potency is only tested with three

compounds (Table 5, p. 76). However, the disclosure is insufficient to allow extrapolation of the limited examples to enable the scope of the tens of thousands of substituted 2-heteroaryl benzimidazoles of the formula I-0.

Within the specification, "specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula." See MPEP § 608.01(p).

(h) *Quantity of experimentation needed to make or use the invention based on the content of the disclosure* - predicting whether a recited compound is in fact one that produces a desired physiological effect at a therapeutic concentration and with useful kinetics, is filled with experimental uncertainty, and without proper guidance, would involve a substantial amount of experimentation (Jordan, V. C. *Nature Reviews: Drug Discovery,* 2, **2003**, pp. 205-213).

It would require undue experimentation for one of ordinary skill in the art to practice the claimed invention in the full broad scope recited in the claims.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to make/or use Applicants' invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC)42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 8-10, 17-19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 discloses **$(R^1—X_5--)_2$** . The claimed $(R^1—X_5--)_2$ is indefinite moreover in view of applicants preferred embodiment. One of ordinary skill in the chemical arts would clearly recognize that the claimed **$(R^1—X_5--)_2$** and the recitation in claim 1 of "R^1 represents aryl, etc.; X_5 represents –O-, etc." means that "$R^1—X_5—$" exists in the compound as exactly the same thing twice. One of ordinary skill would also envision that **$(R^1—X_5--)_2$** can also mean **$(R^1—X_5--)$-$(R^1—X_5--)$**. The disclosure does not provide enough guidance as to the meaning of $(R^1—X_5--)_2$, one of ordinary skill would not be able to understand what it actually encompasses and could not ascertain and interpret the metes and bounds of the patent protection desired as to these term.

8. Claim 1 recites "R^4 independently represents a –C1-6 alkyl and the alkyl may be substituted with the same or different, from 1 to 3 hydroxyls, halogens, -OC(O)-C1-6 alkyls and the alkyl may be substituted with from 1 to 3 halogens, etc…" It is not clear which alkyl is substituted with what. Can both alkyls be substituted with both recited options, or is it the first definition for the first alkyl and the second for the second alkyl? Currently there are different definitions for

the alkyl substitutions. Apparently the first alkyl may be substituted with the first definition “from 1 to 3 hydroxyls, halogens, -OC(O)-C1-6 alkyls” and the second alkyl may be substituted with the second definition “1 to 3 halogens, etc”. If the first alkyl recitation is only defined by the first alkyl definition, then further the elected species is not encompassed by claim 1, because there is nowhere the case for R^4 to be alkoxy group. One of ordinary skill would not be able to understand what the above recitation encompasses and could not ascertain and interpret the metes and bounds of the patent protection desired as to these term.

9. Currently there is no end to claim 1. Claim 1 last word is “having". It seems that claim 1 should continue, however, there is nothing more after “having”.

10. It seems that at the end of claim 1 a proviso is intended, however, it is not clear what are the exceptions. The claim recites “excepting a case where one of X5 is –O-, -S-, -S(O)- or –S(O)2- and the other of X5 is a single bond ..etc.” Is the exception being made for one compound, as in “excepting a case”, or for several compounds? Also, due that the generic compound is recited to have the variables X5 and R1 being different things at the same time, then the compounds that are excepted are not clear. Is R1 aryl in both cases? Moreover, the proviso does not have an end.

11. Claims 8 and 9 disclose the definition for R12. In this definition R12 can be an aliphatic hetero ring, however, it may have 1 or 2 double bonds. Aliphatic compounds, for a person of ordinary skill in the chemical arts, means non-aromatic compounds. One of ordinary skill in the chemical arts can readily recognize that if R12 is aliphatic (non-aromatic) hetero-ring pyrrolidine, the

recitation of the claim that the hetero ring may have 2 doubles bonds will include a pyrrole ring. Pyrrole, however, is aromatic and not aliphatic. Thus, claim 8 is rendered indefinite. It is not clear which compounds are included or excluded from the definition of R12. The disclosure does not provide enough guidance and one of ordinary skill would not be able to understand what it actually encompasses and could not ascertain and interpret the metes and bounds of the patent protection desired as to these term.

12. There are two claims numbered 7. There are two claims numbered 16. There are two claims numbered 17. There is no structure of formula (III-1) in one of claims 17. It is not clear thus what is meant by formula (III-1). Which one of the claims is the one desired for prosecution?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

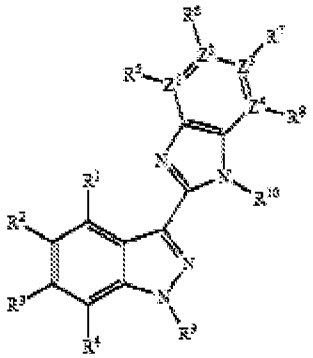
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-3, 8-10, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,064,215 B2.

The prior art teaches compounds having the structural formula I

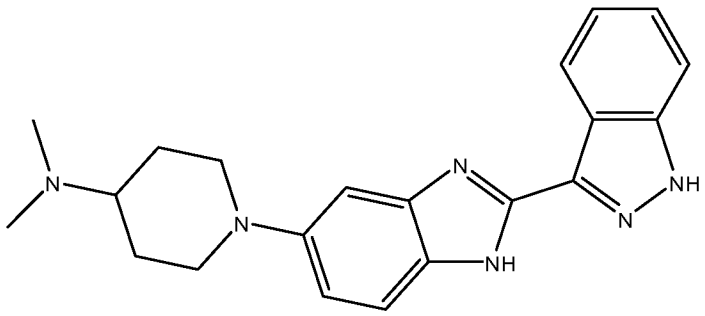


I

. Claim 1 of the patent indicates that Z1, Z2, Z3 and Z4 are all carbons and that R^6 and R^7 are substituted or unsubstituted heterocyclyl groups, heterocyclyloxy groups, aryloxy groups and others. The compounds are used in the treatment of diabetes.

What it lacks is the compounds where R^6 and R^7 are present at the same time as unsubstituted heterocyclyl groups, heterocyclyloxy groups, aryloxy groups as the preferred embodiment. The compounds in the disclosure of the prior art are substituted with one heterocyclyl group, heterocyclyloxy group or aryloxy groups but not with two of these groups at the same time.

Example 1162 of the patent (column 253) has the following structure:



{1-[2-(1H-indazol-3-yl)-1H-benzoimidazol-5-yl]-piperidin-4-yl}-dimethyl-amine. The instant claims suggest exactly the same structure as the above compound, however, with one additional heterocyclic or aryl substituent in the phenyl ring already substituted with piperidine. However, claim 1 of the patent recites that R^6 and R^7 could be heterocyclyl groups, heterocyclyloxy groups and aryloxy groups at the same time. The intended use of the compounds of the instant application is also for the treatment of diabetes. The instant claims are a subgenus of the claims of patent US 7,064,215 B2. A person of ordinary skill in the chemical arts would have envisioned the compounds of the instant invention as the compounds of the prior art further with one heterocyclic or phenyl substituent. A person of ordinary skill in the arts, a chemist practitioner, would have been motivated to add a heterocyclic or phenyl substituent to the substituted benzoimidazole compounds, such as the one above, because the prior art suggests so (it discloses that R^6 and R^7 could be heterocyclyl groups, heterocyclyloxy groups and aryloxy groups at the same time), because the compounds have exactly the same core structure and because such known structures have efficacy against diabetes and diabetes is a disorder that an increasing population of humans suffer. The motivation to make the claimed compounds greatly derives from the expectation that structurally

similar compounds would possess similar properties (i.e. pharmacological use). Both, the instantly claimed compounds and the compounds of US 7,064,215 B2 have exactly the same core structure and are used for treatment of diabetes. Although, applicant's compound differs in that the prior art of US 7,064,215 B2 is more general, the instant claims read on US 7,064,215 B2.

In Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983) the Court noted that "the question under 35 U.S.C. 103(a) is not whether the differences [between the claimed invention and the prior art] would have been obvious" but "whether the claimed invention as a whole would have been obvious."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14 Claims 1-3, 8-10, 17-19 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 18 of copending Application No. 11/988592, claims 1-8 and 10 of copending Application No. 11/99255 and claims 1-15 of copending Application No. 11/666555. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the same subject matter. The instant claims are generic to the other application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Objections

Claims 2-3, 8-10, 17-19 and 24 are objected to because independent claims start with –A- and dependent claims must start with –**The**-. Also, when referring back to a formula or a compound the claim must recite "of the formula (I-1)". See the rest of the claims for any other errors. Appropriate correction is required.

There is currently no claim 12, following claim 11 is claim 13.

Claims 1-19 and 24 are also objected to for containing non-elected subject matter.

The examiner has tried to point out the most visible errors in the claims. However, the examiner invites applicants to review the claims and make them suitable as per the MPEP rules.

Telephone Inquiry

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VALERIE RODRIGUEZ-GARCIA/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626